

and 3,4-diaminohydroxypyrazole; and provided that said composition does not comprise a heterocyclic coupler chosen from indole, indoline, monocyclic pyridine, and phenazine compounds, in a medium appropriate for dyeing keratinous fibers; and

a second compartment containing a second composition comprising at least one enzyme of the laccase type, in a medium appropriate for dyeing keratinous fibers.

II. Status of Claims

Claims 32-36 and 38-69 are pending in the application. Claim 37 has been cancelled by this amendment. Claims 32 and 63-65 have been amended to be more consistent with the specification and original claims. Support for the amendments to claims 32 and 63-65 may be found, for example, in the specification at page 4, lines 7-11. Accordingly, no new matter has been added.

III. Rejection Under 35 U.S.C. § 112

The Office has maintained its rejection of claims 35 and 37, and further rejected new claims 67 and 69 as being indefinite under 35 U.S.C. § 112, second paragraph, for the reasons of record. See final Office Action, p. 2, paragraph 2. Applicants continue to respectfully traverse this rejection for the reasons of record, as well as for the following additional reasons.

Specifically, the Office has concluded, without a single statement of supporting fact, that the term "biotechnology" is "indefinite and its metes and bounds are not understood." See final Office Action, p. 2, paragraph 4. However, mere conclusions cannot meet the Office's initial burden of providing a basis for its rejection. See

M.P.E.P. § 706.03 ("Where a major technical rejection is proper (e.g., lack of proper disclosure, undue breadth, utility, etc.) such rejection should be stated with a full development of the reasons rather than by a mere conclusion coupled with some stereotyped expression."). Mere conclusions are also not amenable with allowing Applicants to make a meaningful reply.

Moreover, "[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

M.P.E.P. § 2173.02. Additionally, the claimed subject matter need only be circumscribed "with a reasonable degree of clarity and particularity." [*Emphasis added*].

Id.

Here, the Office has failed to consider at least the content of the specification and the teachings of the art. For example, a number of documents are cited in the present application, and specifically incorporated by reference. See paragraph bridging pp. 5-6. Each reference relates to the production of a laccase enzyme, including those obtained by biotechnology. Given the disclosure of these non-limiting examples (which are specifically incorporated into the present application by reference) and the evident knowledge of one skilled in the art, it stands to reason that the claimed subject matter is circumscribed "with a reasonable degree of clarity and particularity." *M.P.E.P.* § 2173.04.

Furthermore, one of ordinary skill in the art would have been reasonably apprised of the scope and meaning of the term "biotechnology," as evidenced by definitions

found in technical dictionaries. See, e.g., *Dictionary of Biotechnology* pp. 48-49 (2d Ed., Stockton Press, New York (1992)) (enclosed for the Office's consideration). For example, a relevant part of this dictionary defines the term "biotechnology" as follows:

"The application of organisms, biological systems or biological processes to manufacturing and service industries. This definition has been expanded to include any process in which organisms, tissues, cells, organelles or isolated enzymes are used to convert biological or other raw materials to products of greater value . . ."

Dictionary of Biotechnology, supra.

Thus, when the definiteness of claim language is properly analyzed in light of the content of the specification, the teachings of the art, and the interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made, it is evident that the term biotechnology provides the requisite reasonable degree of clarity and particularity. For at least these reasons, the rejection should be withdrawn.

IV. Rejection Under 35 U.S.C. § 103

Claims 32-69 stand rejected under 35 U.S.C. § 103(a) as unpatentable over WO 97/19998 (Aaslyng) in view of U.S. Patent No. 5,769,903 (Audousset) for the reasons set forth at pp. 2-3 of the outstanding final Office Action. Applicants respectfully continue to disagree with this rejection for the reasons of record, as well as for the following additional reasons.

The Office has cited *In re Kerkhoven* for the proposition that "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be

useful for [the] same purpose in order to form [a] third composition that is to be used for [the] very same purpose". [*Emphasis added*] See final Office Action, p. 3, lines 8-12. However, combining the compositions of Audousset with the compositions of Aaslyng would not result in Applicants' claimed composition. Applicants' claims provide, *inter alia*, that the composition does not comprise a heterocyclic coupler chosen from indole compounds. See, e.g., claim 32. The Audousset reference, on the other hand, teaches a composition comprising "at least one coupler selected from indole couplers of . . . formula (I)." See, e.g., Audousset, column 2, lines 7-15. Therefore, if a composition of Audousset were combined with a composition of Aaslyng, the resulting composition would necessarily include an indole coupler, specifically excluded by Applicants' claims. For this reason alone, the rejection is improper and should be withdrawn.

On the other hand, if the Office is merely attempting to pluck an individual compound from the compositions of Audousset and combine it with the teachings of Aaslyng, *Kerkhoven* does not apply and cannot provide a short-cut to obviousness. As discussed above, *Kerkhoven* merely stands for the proposition that combining two compositions taught to be useful for the same purpose in order to form a third composition used for the very same purpose is *prima facie* obvious. Thus *Kerkhoven* would not apply where, as may be the case in the present application, the Office is attempting to combine individual compounds from various compositions by picking and choosing from each. For this additional reason, *Kerkhoven* cannot supply the requisite motivation, and the rejection should be withdrawn.

The Office additionally argues that ". . . combination for [the] same purpose, of one additive explicitly disclosed in [the] prior art and another suggested by [the] prior art

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is at least prima facie obvious (*In re Susi* 169 USPQ 423)." See final Office Action, page 3, lines 11-13. However, it is not clear from the final Office Action what, if anything, in the references, is being referenced by "one additive explicitly disclosed in prior art" and by "another suggested by prior art." Moreover, the statement regarding "combination for [the] same purpose" seems unrelated to and does not support the Office's proposed rejection. Modifying the oxidative hair dye compositions of Aaslyng by using a heterocyclic dye precursor taught by Audousset is not necessarily the same as combining two additives known for the same purpose. Therefore, if the Office intends to continue applying *Susi* in support of the rejection, Applicants request clarification on this point. In light of these deficiencies, this rejection is improper and should be withdrawn for this reason alone.

Furthermore, and for the above stated reasons, the Examiner's arguments regarding *Kerkhoven* and *Susi* fail to address Applicants' remarks of record that there is no clear and particular motivation for the Aaslyng/Audousset combination. See Amendment Under 37 C.F.R. § 1.111, pp. 5-8. A close reading of the cited references provides support for Applicants' position that there would have been no motivation to haphazardly combine the compositions, or individual ingredients from the compositions, of the references, nor would there be any reasonable expectation of success for doing so, in light of the general unpredictability of the art. This general unpredictability is due, at least in part, to the requirements of oxidative hair dye systems and the incompatibility of certain oxidation bases and couplers.

As discussed by the cited references, in order to be satisfactory, oxidative hair dyes must meet certain requirements. Aaslyng teaches that oxidative hair dyes must be

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very durable to sunlight, shampooing, and other treatments. See Aaslyng, p. 2, lines 3-5. Audousset teaches that oxidative dyes are desired to have "no toxicological drawbacks" and to "allow shades of the desired intensity to be obtained and to have good resistance to external agents (light, inclement weather, washing, permanent waving, perspiration and friction)." See Audousset, column 1, lines 37-44. Further, the dyes should "allow white hairs to be covered" and should "be as unselective as possible, i.e., ... should ... allow the smallest possible difference in coloration to be produced over the entire length of the same keratin fiber, which may indeed be differently sensitized (*i.e.*, damaged) between its tip and its root." See *Id.* at lines 45-51. Notably, Audousset illustrates the unpredictability of the art by pointing out that certain known compositions comprising an oxidation base and a heterocyclic coupler are not entirely satisfactory, in particular, from the point of view of the intensity and staying power of the colorations. See *Id.* at lines 52-65.

Thus, in light of the general unpredictability of the oxidation dyeing arts, there would have been no motivation or reasonable expectation of success to haphazardly combine the compositions of the Aaslyng and Audousset references, as the Office has attempted to do. Similarly, there would have been no motivation or reasonable expectation of success to pluck Applicants' claimed heterocyclic base or coupler from among the ingredients of the carefully formulated compositions of Audousset for use in the compositions of Aaslyng, without some specific teaching or suggestion to do so. Therefore, as no teaching or suggestion has been provided for any kind of modification or combination of the cited references, the rejection under section 103 is improper and should be withdrawn.

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Finally, because there would have been no motivation or reasonable expectation of success for the proposed Aaslyng/Audousset combination, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

V. Conclusion

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Office. Applicants respectfully point out that the final action by the Office presented some new arguments as to the application of the art against Applicants' invention. It is respectfully submitted that the entering of the Amendment would allow Applicants to reply to the final rejections and place the application in condition for allowance. Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Office dispute the patentability of the pending claims. Applicants therefore request entry of this Amendment, the Office's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

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Please grant any extensions of time required to enter this response and charge
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Respectfully submitted,

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APPENDIX TO AMENDMENT OF MAY 2, 2002

Version of amended claims with markings to show changes made, pursuant to 37 C.F.R. 1.121(c)(1)(ii). Claim 37 was cancelled. Claims 32 and 63-65 were amended, as follows:

32. (Amended) A composition for the oxidation dyeing of keratin fibers, comprising:

(a) at least one oxidation dye chosen from heterocyclic oxidation bases, heterocyclic couplers, and acid addition salts of said oxidation dyes; and

(b) at least one laccase-type enzyme,
provided that said composition does not comprise a heterocyclic oxidation base [is not] chosen from 4,5-diamino-6-hydroxy-pyrimidine and 3,4-diaminohydroxy-pyrazole, and

provided that said composition does not comprise a heterocyclic coupler [is not] chosen from indole, indoline, monocyclic pyridine, and phenazine compounds.

63. (Amended) A method of dyeing keratinous fibers, comprising the step of applying at least one dyeing composition to said keratinous fibers for a sufficient time to achieve a desired coloration, wherein said at least one dyeing composition comprises:

(a) at least one oxidation base chosen from heterocyclic oxidation bases, heterocyclic couplers, and acid addition salts of said oxidation dyes, provided that said

dyeing composition does not comprise a heterocyclic oxidation base [is not] chosen from 4,5-diamino-6-hydroxy- pyrimidine and 3,4-diaminohydroxypyrazole; and provided that said dyeing composition does not comprise a heterocyclic coupler [is not] chosen from indole, indoline, monocyclic pyridine, and phenazine compounds; and

- (b) at least one enzyme of the laccase type.

64. (Amended) A method for dyeing keratinous fibers comprising the steps of:

- (a) storing a first composition;
- (b) storing a second composition separately from said first composition;
- (c) mixing said first composition with said second composition to form a mixture; and
- (d) applying said mixture to said keratinous fibers for a sufficient time to achieve a desired coloration;

wherein said first composition comprises at least one oxidation base chosen from heterocyclic oxidation bases, heterocyclic couplers, and acid addition salts of said oxidation dyes, in a medium appropriate for dyeing keratinous fibers, provided that said first composition does not comprises a heterocyclic oxidation base [is not] chosen from 4,5-diamino-6-hydroxy-pyrimidine and 3,4-diaminohydroxypyrazole; and provided that said first composition does not comprise a heterocyclic coupler [is not] chosen from indole, indoline, monocyclic pyridine, and phenazine compounds; and

wherein said second composition comprises at least one enzyme of the laccase type, in a medium appropriate for dyeing keratinous fibers.

65. (Amended) A multicompartment device or a dyeing kit, comprising:
- a first compartment containing a first composition comprising at least one oxidation base chosen from heterocyclic oxidation bases, heterocyclic couplers, and acid addition salts of said oxidation dyes, provided that said composition does not comprise a heterocyclic oxidation base [is not] chosen from 4,5-diamino-6-hydroxypyrimidine and 3,4-diaminohydroxypyrazole; and provided that said composition does not comprise a heterocyclic coupler [is not] chosen from indole, indoline, monocyclic pyridine, and phenazine compounds, in a medium appropriate for dyeing keratinous fibers; and
- a second compartment containing a second composition comprising at least one enzyme of the laccase type, in a medium appropriate for dyeing keratinous fibers.

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